Remarks/Arguments:

Responsive to the Office Action identified above, claims 1, 2, 5, 6, 14, 12 and 16 are now presented for further consideration. Claims 3, 4, 7-11, 13 and 15 stand canceled.

Rejection under 35 U.S.C §112

Claims 1-6, 11,12, and 14-16 were rejected as indefinite in the definition of the glucosamine material permitted in the claims. This ground of rejection has now been obviated by clarifying the permitted definitions in claims 1 and 16. Withdrawal is respectfully requested.

Rejections under 35 U.S.C §102

Claims 1-4, 14 and 15 were rejected as being anticipated by Meissner, U.S. Patent No 4,772,591. The office action alleged that Meissner disclosed administration of glucosamine and Nalfon® for the treatment of pain. This ground for rejection has been obviated by the cancellation of claim 15 and amendment of claim 1 and claims dependent thereon, which no longer cover compositions including or using Nalfon.

This ground of rejection (as well as its use as a basis for an obviousness rejection (discussed below) is also traversed for the following reasons. Example 11 of Meissner, to which the office action refers discloses the use of 2000 mg of glucosamine per day together with 600 mg Nalfon 4 times per day (a daily dose of 2400 mg of Nalfon. The weight ratio of Glucosamine to Nalfon on a daily basis is thus 2000/2400, i.e., 0.83 :1. That ratio is substantially below the range claimed by applicants which has been shown to be required to obtain synergistic pain relief. Withdrawal is respectfully requested.

Claims 1-3 were rejected as being anticipated by Falk, U.S. patent 5,811,410. This rejection is respectfully traversed. Falk discloses compositions comprising NSAIDS and hyaluronic acid. Applicant's claims are limited to compositions which contain a glucosamine material (which does not include hyaluronic acid) and either ibuprofen or ketoprofen as analgesics. There is no teaching or suggestion in Falk which would suggest to one of ordinary skill in the art the use of the claimed combinations. In order for a disclosure to anticipate, it must teach each and every limitation of the claim in question. The Falk reference simply does not comply with the legal requirements under 35 U.S.C. § 102, regardless of whether there is or is not a disclosure precluding oral administration. Withdrawal is respectfully requested.

Claims 1, 2, 14 and 15 were rejected as anticipated by Hammerly, U.S. Patent No. 6,608,041 under 35 U.S.C. § 102(e). Applicants respectfully traverse this rejection for the following reasons.

Hammerly teaches a composition (and method of treatement) for treatment of osteoarthritis comprising a chondroprotective component and an analgesic component wherein the chondroprotective component is naturally occurring and may be a glucosamine material as defined in Applicants' claims, and the analgesic component is acetaminophen or its derivatives or analogs. Specifically named analgesics include acetaminophen, codeine, morphine, demerol, Percodan, aspirin, dihydrocodeinone, Dilaudid, Dicodid, and Fentanyl (see examples 1-18. There is no teaching or suggestion which would motivate one of ordinary skill in the art to employ any NSAID as the analgesic component and certainly no teaching or suggestion motivating the use of ibuprofen or ketoprofen.

Further, there is nothing in the reference which would teach or otherwise motivate one of ordinary skill in the art to employ a chondroprotective and analgesic component in ratios which produce synergistic analgesia over that which is obtained from the analgesic component alone. As dicsclosed at col. 4, line 20 - 34, when glucosamine sulfate is used, it is used at a daily dose of 1500 milligrams/day per 150 pounds of body weight. The acetaminophen needed is stated to be 1000 to 2000 milligrams two to four times per day. Thus the glucosamine sulfate to analgesic weight ratio for the daily dose is 1500/2000 to 1500/8000, which corresponds to a value of 0.75:I to as low as 0.1875:1. As shown by applicants data a ratio of at least 1:1, and preferably 2:1 is required in order to obtain the synergistic pain relief that is required by Applicants' claims. These ratios are neither taught no suggested by the Hammerly reference.

Finally, it is unclear if acetaminophen or its analogs are capable at any ratio of providing synergistic pain relief claimed by Applicants. Examiner's attention is directed in this regard to the comments and data reported by Applicants at page 14, line 20 through page 16, including the conclusion at page 14, lines 35-38:

> Thus, combinations of glucosamine with aspirin, acetaminophen, diclofenac or tramidol at those ratios are sub-additive and thus are, by definition, excluded from the scope of the invention and from the claims set forth below,...

For the foregoing reasons, the rejection based on anticipation by Hammerly is respectfully traversed. Withdrawal is respectfully requested.

Rejections under 35 U.S.C. § 103

Claims 1-4, 12, 14, and 15 were rejected as obvious over Messner, U.S. Patent No. 4,772,591, the relevant teaching of which is set forth above. In this rejection, the office action specifically refers to claim 12 which includes in the composition various active ingredients other than the glucosamine material and the analgesic compound. The Office action alleges that it would be obvious from Meisner to add such ingredients because, for example one treating osteoarthritis would be motivated to add such ingredients for additive effects. In this regard, attention is drawn to column 6, lines 28 - 32 which specifically teaches the addition of other active ingredients to the formulation taught by Meisner. However, for reasons set forth above with respect to the anticipation rejection, claim 12 of the present application is a dependent claim the patentability of which depends on the patentability of claims 1 and 2, both of which require ratios of the glucosamine and analgesic components which produce synergistic pain relief. As indicated above Meissner applicable teachings is outside the claimed range.

Accordingly, the rejection based on obviousness over Meisner is traversed and should be withdrawn.

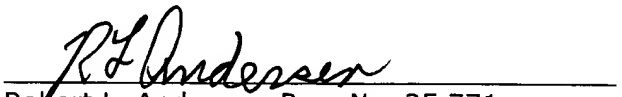
Claims 1-6, 11,12, and 14-16 were all rejected under 35 U.S.C. § 103 over Falk ('410 above) in view of Roentsch, U.S. Patent No. 5,654,337. This ground for rejection is respectfully traversed.

This ground of rejection appears to be based on some (unidentified) teaching in Roentsch to motivate one of ordinary skill in the art to modify the teaching of Falk to produce the synergistic compositions now claimed by applicant. The undersigned has spent considerable time trying to understand how modification of either of these references according to a clear teaching of the other would produce applicants claimed compositions. Neither of them use a glucosamine material as defined in applicants claims, neither of them relate to a composition for oral administration. Neither of them combine Ibuprofen or Ketoprofen with a glucosamine compound, and neither of them teach or suggest ratios which produce synergistic pain relief. Applicants respectfully request further explanation of the precise basis of this

rejection. Absent such an explanation, Applicants respectfully submit that this rejection is without factural or legal basis and request withdrawal thereof.

Applicants acknowledge with thanks Examiner's helpful comments and indication of allowability for claims to a synergistic composition and/or method of use of ibuprofen or ketoprofen and a monomeric glucosamine material recited in the claims. Applicants have amended the claims in conformity with Examiner's remarks and respectfully submit that as currently amended the claims are now in condition for allowance. Favorable action and a prompt indication of allowability is respectfully requested.

Respectfully submitted,



Robert L. Andersen, Reg. No. 25,771
Attorney for Applicants

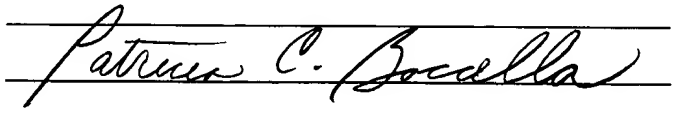
RLA/pb

Dated: September 21, 2004

P.O. Box 980
Valley Forge, PA 19482
(610) 407-0700

The Commissioner for Patents is hereby authorized to charge payment to Deposit Account No. **18-0350** of any fees associated with this communication.

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail, with sufficient postage, in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on: September 21, 2004



P_I:\TUNA\566 US\AMEND03.DOC